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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,684	09/15/2003	Yong Kyun Cho	P-9894.02	9786

7590 05/10/2005
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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/662,684		CHO ET AL.	
	Examiner		Art Unit	
	Navin Natnithithadha		3736	-

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02072005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1-12 and 29-36 were canceled.
2. Claims 13-28 are pending.

Response to Arguments

3. Applicant's arguments with respect to claims 13, 15-22, and 24-35 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

4. The information disclosure statement filed 07 February 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement does filed 07 February 2005 is missing a copy of the non-patent literature publication (Garrigue et al). Thus, the document was not considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 13-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Street et al, US 6,589,188 B1.

In regards to claims 13 and 22, Street teaches an implantable medical device (see col. 4, lines 11-13), comprising:

a sensor 12 for measuring one or more physiological signals (see col. 5, lines 48-53 and col. 6, lines 4-6); and

a processor for archiving ("extracting") for a periodic breathing sequence include any or all of the following: time/breathes of hyperpnea per cycle, time/breaths of hypopnea per cycle, time of apnea per cycle, largest hyperpnic excursion per cycle, largest hypopnic excursion per cycle, number of cycles the sequence was sustained and average cycle length of periodic breathing in the sequence ("an average cycle length and a frequency of at least one of Cheyne-Stokes respiration and periodic breathing").

In addition, Street teaches automatic telemetry for transmission of data from the device ("telemetry device for transmitting the data set") (see col. 8, lines 6-14). Street does not explicitly teach a memory unit for storing the physiological data. However, Street teach

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first processing the sensor 12 signal in a signal processor 14 to extract data for analysis (see col. 6, lines 11-13) and archiving the data for analysis (see col. 7, lines 52-60).

The processing and archiving of data would inherently involve a memory unit, such as a ROM or database, which are well known in the art.

As to claims 15 and 21, Street teaches interrogation of the device to retrieve archived data (see col. 8, lines 6-7).

As to claims 16-20 and 24-28, Street teaches sensors for measuring the following physiological parameters: respiratory tidal volume, respiratory rate, arterial oxygen saturation, and heart rate, which would includes sensors such as impedance plethysmography sensor, and electrocardiogram sensor (see col. 3, lines 21-47, col. 4, lines 13-19, col. 5, lines 54-56, and col. 6, lines 6-11). All of the claimed sensors are examples of the sensors disclosed by Street.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 14 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al, US 6,589,188 B1, as applied to claims 13 and 22 above, and further in view of Colla et al, US 6,091,973 A.

As to claims 14 and 23, Street does not disclose the processor extracts arousals from the data corresponding to the sleep respiratory events and stores the wake events in memory. However, Colla teaches a processor 18 for processing physiological data to detect ("extract") arousal episodes from the data and stores this data into a memory device 20 (see col. 2, lines 20-29, col. 4, lines 10-36, and col. 5, lines 26-48). The physiological data can be obtained by pulse oximetry, ECG techniques, impedance techniques, blood pressure measuring techniques, or plethysmography techniques (see col. 4, lines 10-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Street's processor to extract arousals from the physiological data in order to properly monitor apnea.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 13, 15-20, 22, and 24-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 9, and 10 of U.S. Patent No. 6,641,542 A (Cho et al) in view of Street et al, US 6,589,188 B1.

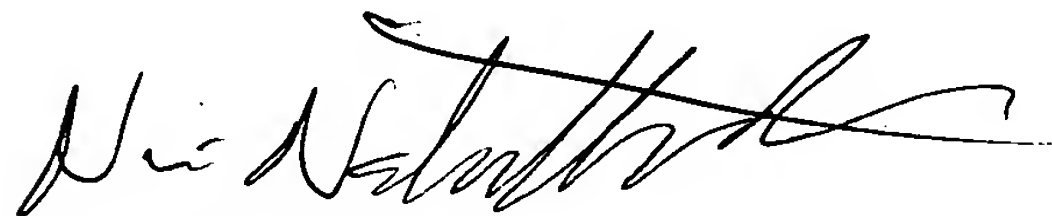
Cho et al teaches the claimed subject matter except for the medical device is implantable and the medical device comprising: a telemetry device for transmitting the data set or sleep respiratory events from the processor. However, Street teaches an implantable medical device (see col. 4, lines 11-13) including automatic telemetry for transmission of data from the device ("telemetry device for transmitting the data set") (see col. 8, lines 6-14). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Cho et al device in order to retrieve archived data from the implanted device to a physician (see Street, col. 8, lines 6-14).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha
Patent Examiner
GAU 3736
06 May 2005